DEVICES FOR THE TREATMENT AND/OR DIAGNOSIS OF TEMPOROMANDIBULAR JOINT DYSFUNCTION AND/OR OROFACIAL PAIN

CLASSIFICATION GRID INTRODUCTION

August 1998 Dental Panel Meeting

The Food and Drug Administration is providing a table of products for the treatment and/or diagnosis of TMD and/or Orofacial Pain that it intends to discuss at the August 1998 meeting of the Dental Devices Advisory Committee. This is a redraft of the table that was provided prior to the November 1997 meeting of the Panel for discussion purposes.

The table is in the form of a grid of information. The grid identifies the generic name of a product, FDA's determination whether the product is a medical device, relevant classification regulations in 21 CFR, any classification description in 21 CFR, and any specific TMD and or orofacial pain indications for use in product labeling.

FDA intends to request the Panel to provide a classification recommendation on those products that are medical devices which are intended for the treatment and/or diagnosis of TMD and/or orofacial pain and which do not already fall within a present device classification.

FDA has determined that several generic types of products that are listed are not subject to classification, while others are subject to classification. Each numbered item refers to the reason for the device classification or the reason the device does not require classification. FDA has determined that some products are not subject to classification for the following reasons:

1. The generic type of product is not a medical device as defined in the Food, Drug, and Cosmetic Act.

2. The generic type of device is classified, the general intended use in the classification regulation encompasses the use of the device for the treatment and/or diagnosis of TMD and/or orofacial pain, and there are no TMD specific indications for use in labeling of any legally marketed devices that FDA has identified within the generic type. Therefore, this generic type of device does not require classification.

3. The generic type of device is classified, there are legally marketed devices with TMD related claims, and the FDA has determined that any legally marketed devices within this generic type with a TMD and/or orofacial pain related indication for use is within the generic device classification. Therefore, FDA's finding may modify previous determinations on the classification status of specific devices and require notification to the affected parties.

FDA has determined that some devices are subject to classification for the following reasons:

4. The specific indication for the treatment and/or diagnosis of TMD and/or orofacial pain within the generic type of device is not encompassed by the general indication for use nor is the specific product. Because of this, new types of safety and effectiveness issues are of concern and therefore classification is required. The center will assess any differences in indications in terms of safety and effectiveness questions that the different indication may raise. After consideration of these factors and recommendations from experts a classification may be recommended.

5. The generic type of device is not classified. There are no related classification generic types.

Notwithstanding the classification and labeling of devices, health care practitioners who are authorized to prescribe and administer medical devices may use legally marketed devices for any purposes they believe are appropriate for their patients. Therefore, there may be instances where products and devices are being used for the treatment and/or diagnosis of TMD and/or orofacial pain, but are not labeled for such use. These uses are not under the parameters of an FDA classification, clearance or approval, but are considered the practice of medicine. Persons who market and promote new devices or new uses for devices are subject to premarket requirements. The public should refer to Section 214 of the Food and Drug Administration Modernization Act of 1997 for more information in this regard.

PRODUCTS CONSIDERED FOR CLASSIFICATION BY THE DENTAL PRODUCTS PANEL

* See the "Classification Grid Introduction" for the definition of each code number

Generic Product Type	Is this a device ?	Existing Classification Regulation Relevant to Generic Product Type		TMD Specific Intended Uses in Legally Marketed Devices	Does Device Require Classification ?	Reason *
		CFR Citation	Classification Regulation			
Electromyograph	Yes	EMG, 890.1375 (Physical Medicine)	*Class II*, A device intended to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves and to monitor and display electrical activity produced by nerves, for the diagnosis and prognosis of neuromuscular disease.	Evaluate muscle contraction, quantify abnormalities of muscle position for jaw relations, verify balance of jaws, (balances muscles of occlusion, face, and neck, that are associated with occlusion); Monitor jaw position and record relationship of mandible to base of skull	No	3
Sonogram for Diagnosis in TMD/Orofacial Pain	Yes	Electronic Stethoscope, 870.1875 (Cardiovascular)	*Class II*, An electrically amplified device used to project the sounds associated with the heart, veins, and other internal organs.	To classify and interpret specific joint sounds in the diagnosis and treatment of TMD/Orofacial pain, to measure and record sounds emitted from the TMJ as means of assessing TMJ status	Yes, for the intended use of classifiying and interpreting specific joint sounds	4
Kinesiograph	Yes	Pantograph, 872.3730 (Dental) and Goniometer, 888.1500 (Orthopedic)	Pantograph, *Class I* (exempt), A device intended to be attached to a patient's head to duplicate lower jaw movements to aid in construction of restorative and prosthetic dental devices. Goniometer, *Class I* (exempt), A device intended to evaluate joint function by measuring and recording ranges of motion, acceleration or forces exerted by a joint.	Identify freeway space, identify mandibular rest position, record relationship of the mandible to base of skull, and interpretation of jaw movements in diagnosis and treatment of TMD/Orofacial pain	Yes	4

Generic Product Type	Is this a device ?	Existing Classification Regulation Relevant to Generic Product Type		TMD Specific Intended Uses in Legally Marketed Devices	Does Device Require Classification ?	Reason
		CFR Citation	Classification Regulation			
Transcutaneous Electronic Nerve Stimulator for Pain Relief	Yes	TENS, 882.5890 (Neurology)	*Class II*, A device used to apply an electrical current to electrodes on a patient's skin to treat pain.	Relief of chronic muscle pain, relief of TMJ associated muscle spasms,	No	3
Therapeutic Ultrasound	Yes	Ultrasound and Muscle Stimulator, 890.5860 (Physical Medicine)	*Class II*, A device for applying therapeutic deep heat for selected medical conditions, such as relief of pain, muscle spasms and joint contractures, also to pass electrical currents through the body area to stimulate or relax muscles. All other uses for treatment of medical conditions by means other than generation of deep heat within body tissues and the stimulation or relaxation of muscles are *Class III*.	None	No	2
Thermography	Yes	Powered Temperature Measurement Device, 882.1570 (Neurology)	*Class II*, A device which contains a power source and is used to measure differences in temperature between two points on the body.	None	No	2
Imaging Devices, including: Dental X-ray, Computed Tomography, MRI, Diagnostic Ultrasound	Yes	Dental: Extraoral and Intraoral X-ray System, 872.1800 and 872.1810 Radiology: Computed Tomography, 892.1750; MRI, 892.1000; Ultrasound, 892.1550 and 892.1560	*Class II*, Devices used to radiographically observe and record conditions of orofacial structures.	No	No	3
Psychological Tests	No					
Occlusal Registration	Yes	Various Dental Materials: Impression Material, 872.3660; Dental Wax, 872.6890 and Tooth Shade Resin Material, 872.3690 (Dental)	Impression Material, *Class II*, A device composed of materials such as alginate or polysulfide intended to be placed on a pre-formed impressions tray and used to reproduce the structures of a	None	No	2

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		CFR Citation	Classification Regulation			
Occlusal Registration (cont.)			patient's teeth and gums, for study and for production of restorative prosthetic devices. Dental Wax, *Class I* (exempt), A device made of wax intended to construct patterns and make a pattern of a patient's bite. Tooth Shade Resin *Class II*, A device composed of materials such as bis-GMA intended to restore carious lesions or structural defects in teeth.			
Mechanical TMD Devices	Yes	Nonmeasuring Exercise Equipment, 890.5370 and Powered Exercise Equipment, 890.5380 (Physical Medicine and Rehabilitation)	Non Measuring Exercise Equipment *Class I*, (exempt), A device intended for medical purposes, such as to redevelop muscles or restore motion to joints. Powered Exercise Equipment, *Class I* (exempt), A device intended for medical purposes such as to redevelop muscles or restore motion to joints.	Devices intended to be used with patients with limited jaw opening secondary to TMD/Orofacial pain	No	3
Iontophoresis Device	Yes	Iontophoresis, 890.5525 (Physical Medicine)	*Class II*, A device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis, or for other uses if the labeling of the drug intended for use with the device bears adequate directions for use with that drug. *Class III*, A device that is intended to use a direct current to introduce ions of soluble salts or other	None	No	2

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		CFR Citation	Classification Regulation			
Iontophoresis Device (cont.)			drugs into the body for medical purposes other than those specified above.			
Galvanic Stimulation Products	Yes	Galvanic Skin Response Measurement Device, 882.1540 (Neurology) and Powered Muscle Stimulator, 890.5850 (Physical Medicine)	Galvanic Skin Response Device, *Class II*, A device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin. Powered Muscle Stimulator, *Class II*, An electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes.	None	No	2
Software Programs that are used in medicine and are intended to affect the diagnosis and treatment of patients	Yes	• Software as a component of a medical device is regulated according to the requirements of its parent device • Computer products which are medical devices and not components, parts or accessories of other articles are themselves medical devices and are subject to four levels of regulatory control: 1. General Purpose: a product not labeled or promoted for medical use, but by its application in health care meets the definition of a medical device. ⇒ Example: database management system ⇒ These types of computer products are not regulated. 2. Computer products manufactured by licensed practitioners in their practice ⇒ Example: exchange information on public "bulletin boards" ⇒ These types of computer products are not commercially distributed and are not regulated.			No	Regulated per Agency's software guidances

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Software Programs that are used in medicine and are intended to affect the diagnosis and treatment of patients (cont.)		3. Computer Products used in teaching and non-clinical research. ⇒ Example: computer products that cover development efforts which have not progressed to the stage of human experimentation. ⇒ These types of computer products are not regulated. 4. Future exemptions: Previously unclassified information management products, knowledge based systems, artificial intelligence and other types of decision support systems that are intended to involve competent human intervention before any impact on human health occurs will not be regulated.				